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PATENT APPLICATION
DOCKET NO.: 1440.1024-001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Terry B. Strom and Xin Xiao Zheng

Application No.: 09/576,944 Group Art Unit: 1644

Filed: May 22, 2000 Examiner: P. Gambel

Title: TRANSPLANT TOLERANCE BY COSTIMULATION BLOCKADE AND T-CELL ACTIVATION-INDUCED APOPTOSIS

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Harry
Jul. 28, 01

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231

on 7.18.01 Wendy Morrissey
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REPLY TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Responsive to the Restriction Requirement dated May 30, 2001, the claims of Group II (Claims 11-14), drawn to compositions comprising a costimulation blockade agent, are elected for prosecution. Although the Restriction Requirement lists Claim 10 in both Group I and Group II, it appears that the claim properly belongs in Group I. Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the non-elected inventions. Applicants do not hereby abandon or waive any rights in the non-elected inventions.

Responsive to the requirement for an election of species, Applicants hereby elect, with specific traverse, Species "B", anti-CD40L antibodies, for prosecution on the merits. In response to the request to indicate all claims readable on the elected species, Applicants state that pending Claims 1-21 apply to the elected species.

For the reasons set forth in detail below, Applicants traverse the requirement for election of species and respectfully request reconsideration and withdrawal of the requirement. Further,

Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the non-elected species. Applicants do not hereby abandon or waive any rights in the non-elected species.

An extension of time to respond to the Restriction Requirement is respectfully requested. A Petition for an Extension of Time and the appropriate fee are being filed concurrently.

Criteria for Restriction

The necessary criteria for a proper restriction requirement have been clearly defined. Each restriction must meet two separate requirements. These requirements reflect both the statutory basis for restriction under 35 U.S.C. § 121 and its discretionary nature. The criteria are described in the Manual of Patent Examining Procedure, 7th Edition, at § 803, in relevant part, as follows:

> There are two criteria for a proper requirement for restriction between patentably distinct inventions:
>
> (A) The inventions must be independent...or distinct as claimed; and
>
> (B) There must be a serious burden on the examiner if restriction is required...

Basis for Present Restriction Requirement

The Examiner states at paragraph 5 of the Action, that "[t]his application contains claims directed to the following patentably distinct species of the claimed Groups I/II: wherein the costimulation blockade is:

A) anti-CD40 antibodies,

B) anti-CD40L antibodies,

C) anti-B7 antibodies,

D) anti-CD28 antibodies,

E) anti-CTLA-4 antibodies,

F) B7-Ig and soluble extracellular domain proteins thereof,

G) CD28-Ig and soluble extracellular domain proteins thereof,

H) CD40-Ig and soluble extracellular domain proteins thereof,

I) CD40L-Ig and soluble extracellular domain proteins thereof,

J) CTLA4-Ig and soluble extracellular domain proteins thereof,

H) [sic] costimulation blockade drugs or

I-?) [sic] combinations thereof as it reads on the recitation of "at least one".

The Examiner states that these species are distinct because their structures and modes of action are different, and that Applicants are required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits, to which the claims shall be restricted if no generic claim is finally held to be allowable. According to the Examiner, currently, Claims 1, 15 and 16 are generic.

Restriction Is Not Required For Species 'A', 'B', 'H' and 'I' of The Instant Application

Applicants respectfully disagree that election is required in this application between species 'A' (anti-CD40 antibodies), 'B' (anti-CD40L antibodies), 'H' (CD40-Ig and soluble extracellular domain proteins thereof), and 'I' (CD40L-Ig and soluble extracellular domain proteins thereof), because no serious burden would be placed on the Examiner by examining these species concurrently.

As a preliminary matter, it should be noted that there is a second set of species labeled 'H' (costimulation blockade drugs) and 'I' (combinations) in the Requirement. It appears that this second set, which appear after species 'J', is mislabeled, and should be labeled 'K' and 'L'. In this traversal, Applicants refer to the first, properly labeled, species 'H' and 'I'.

The claimed invention of Group II relates to a composition comprising at least one costimulation blockade agent and rapamycin, or a biologically active derivative thereof. As stated on page 9 of the specification, costimulation refers to secondary signaling necessary to T-cell activation, and that examples of costimulation include signaling involving the interaction of B7 and CD28 (or CTLA4), and signaling involving the interaction of the CD40 molecule and the T cell surface molecule CD40 ligand (CD40L). Blockade of these costimulation signals produces potent immunosuppression (page 4). On page 9, the specification states that costimulation blockade agents include any drug, protein, antibody or molecule such as a soluble ligand of a costimulation receptor such as CD40 and CD40L, or a hybrid or mutant molecule or a fusion protein that blocks a costimulation protein interaction, or any substance that would inhibit, block or prevent the intracellular signaling resulting from a costimulation protein interaction. The extracellular domains of the surface proteins in soluble form, including soluble extracellular CD40 and CD40L domain proteins, and fusion proteins, such as CD40-Ig and CD40L-Ig, are specifically discussed on page 10.

It is Applicants' understanding that the purpose of an election of species is for searching, and that the Examiner would first search in the area of art pertaining to the elected species. If no art that would potentially defeat the patentability of the elected species is found, the Examiner would then continue to search in any area of art pertinent to the non-elected species.